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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/931,449	ARCOT, SANTOSH S.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- Th MAILING DATE of this communication app ars on the cover sh et with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-29,35 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5-29,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on May 2, 2003 has been entered. The claims pending in this application are claims 3, 5-29, 34, and 35. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the amendment filed on May 2, 2003.

Specification

2. Claims 3 and 5 are objected to because of the following informality: from the claims, it appears that two contacting step (one is in the beginning and another one is in the last paragraph of the claims) are identical, the examiner suggests applicant to cancel one of contacting steps.

3. Claim 23 is objected to because of the following informality: "the oligonucleotide probes" should be "the oligonucleotides" in order to correspond to "oligonucleotides" in claim 10.

4. The substitute specification filed May 2, 2003 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) since applicant does not filed a clean copy without markings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3, 5-29, 34, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 3 and 5 are rejected as vague and indefinite in view of the phrase "at least one of detecting the presence of the spectrally addressable ligated products or analyzing the nucleic acid sequence of the spectrally-addressable ligated products" because it is unclear what it intended. "at least one of " in the phrase needs to be deleted in order to understand the phrase. "at least one of " in the phrase causes the phrase confusing. Please clarify.

Response to Arguments

In page 16 of applicant's remarks, applicant argues that "[T]he phrase 'least one of ' denotes that, at a minimum, one of the elements recited after the phrase must be included and that, at a maximum, all of the elements may be included. Hence, Applicant submits respectfully that the language 'at least one of 'preceding the recitation of 'detecting the presence of the spectrally addressable ligated products or analyzing the nucleic acid sequence of the spectrally-addressable ligated products' clearly delineates the metes and bounds of the scope of the invention as claimed in Claim 1, now Claims 3 and 5.".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because "at least one of " in the phrase make the phrase confusing and deletion of "at least one of " in the phrase makes a much better English sentence.

8. Claim 3 is rejected as vague and indefinite because the beginning of the claim and the end of the claim do not correspond each other. The beginning of the claim requires that a sample suspected of containing one target nucleic acid sequences contacts with one subset of spectrally-addressable bound probe. However, the end of the claim requires two target nucleic acid sequences and two subsets of spectrally-addressable bound probes. Please clarify.

9. Claim 5 is rejected as vague and indefinite because the beginning of the claim and the end of the claim do not correspond each other. The beginning of the claim requires that a sample suspected of containing one or more target nucleic acid sequences contacts with one subset of free probe. However, the end of the claim requires that two target nucleic acid sequences and two subsets of spectrally-addressable bound probes. Please clarify.

10. Claim 6 is rejected as vague and indefinite because claim 5 and claim 6 do not correspond each other. The end of claim 5 requires that the sample contacts with two subsets of free probes and claim 6 only requires that portion of the sample contacts with either the first subset of free probe or the second subset of free probe. Please clarify.

11. Claim 8 is rejected as vague and indefinite. Since the same amount of fluorescent dye is incorporated into each bound probe, each bound probe can have the same amount of fluorescent dye. Therefore, one subset of spectrally-addressable bound probes can not be distinguishable from other subsets of spectrally-addressable bound probes based at least on the relative amount of the at least one fluorescent dye incorporated into the spectrally-addressable bound probe of the subset, which is different from what the claim is directed. Please clarify.

Response to Arguments

In page 17, second paragraph of applicant's remarks, applicant argues that "[A]pplicant submits respectfully that the language of the claim includes within its scope the condition in which the various subsets of spectrally-addressable bound probes incorporate different amounts of dye (although each bead within each subset has substantially the same amount of the dye as each other bead of the same subset) and are, thus, distinguishable one from another based on that differing amount of dye.".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because that the claim does not indicate that "the various subsets of spectrally-addressable bound probes incorporate different amounts of dye" as suggested by applicant. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. Claim 10 is rejected as vague and indefinite in view of the phrases "the bound probes comprise a microsphere and the bound probes of a given subset further comprise a modifier moiety, which is used for coupling a bound probe to a microsphere" in (ii) of step (a) because it is unclear what it intended if f the examiner compares the definition of "bound probe" in the specification (see page 9), Figures 1 and 6, and applicant's arguments in page 3, second paragraph of applicant's remarks filed on August 22, 2002 with above phrases in this claim. According to the definition of "bound probe" and applicant's arguments, bound probe is "a probe which is

bound to a solid support, and in which the solid support is labeled for detection". In other word, bound probe is a probe that is attached a labeled solid support, which corresponds to the first part of the phrase in (ii) of step (a) wherein the bound probe comprising a microsphere. However, the phrase "coupling a bound probe to a microsphere" in (ii) of step (a) requires to couple a bound probe to another microsphere. Since the solid support can be particle, 5' and 3' of the bound probe in step (c) appear to have attached particles, in the examiner's opinion, it is impossible that such bound probe can ligate with free probe because both ends of bound probe have been blocked by the particles. Furthermore, according to Figures 1 and 6, no such bound probe is taught by the specification. Please clarify.

13. Claim 10 is rejected as vague and indefinite in view of the phrase "the bound probes comprises a microsphere" in (ii) of step (a) and (iii) of step (a) because it is unclear what it intended. Since (ii) of step (a) indicates that the bound probes only comprise one kind of microspheres, it is unclear how microspheres in (iii) of step (a) can distinguish each other and (ii) of step (a) and (iii) of step (a) do not correspond each other. Please clarify.

14. Claim 15 is rejected as vague and indefinite in view of the phrase "the bound probes comprises a microsphere" in (ii) of step (a) of claim 10 and claim 15. Since (ii) of step (a) indicates that the bound probes only comprise one kind of microspheres, it is unclear how the mixture in claim 15 comprises at least two subsets of microspheres and claim 10 and claim 15 do not correspond each other. Please clarify.

15. Claim 16 is rejected as vague and indefinite because it is unclear what it intended. Does the phrase " the bound probes differ in that the nucleotide found at one end of one subset differs

from that found at the corresponding end of the other subset" mean that the nucleotide sequences at one end of one subset of bound probes are different from the nucleotide sequences at one end of another subset of bound probes or this phrase mean something else? Does the phrase "wherein the nucleotide sequences comprising the at least two subsets of bound probes are otherwise substantially identical" mean that the nucleotide sequences at one end of one subset of bound probes are substantially identical to the nucleotide sequences at one end of another subset of bound probes or this phrase mean something else? Please clarify.

Response to Arguments

In page 19, third paragraph of applicant's remarks, applicant argues that "[C]laim 16 adds the limitation that the nucleic acid sequences amongst the various subsets of free probes and bound probes are substantially identical, with the exception that the nucleotide found at one end of the bound probes, and at the corresponding end of the free probes, is different amongst the various subsets. Thus, Applicant submits respectfully that the meaning of Claim 16 as filed is clear and definite".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Although the examiner understands what applicant wants in claim 16 after reviewing applicant's arguments, the limitations recited in the arguments are not recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner suggests applicant to add the limitations recited in his arguments into claim 16 in order to overcome this rejection.

16. Claim 20 is rejected as vague and indefinite because it is unclear what it intended. The phrase "the nucleotide and the detectable label found at opposite ends of one set differing from that nucleotide and the detectable label found in the corresponding ends of the other set" is unclear because, from claim language of this phrase, it is unclear whether free probes have one detectable label or two detectable labels. Does this phrase mean the nucleotide sequences at opposite ends of one set differing from that nucleotide sequences in the corresponding ends of the other set or this phrase mean something else? Please clarify.

Response to Arguments

In page 20, first paragraph of applicant's remarks, applicant argues that "[E]ach probe in each set of free probes comprises a nucleotide sequence having two opposite ends. At one end is a detectable label. At the other, opposite, end is a single nucleotide. The probe ends having the single nucleotide of one set correspond to the probe ends having the single nucleotide in another set. Likewise, the ends with the detectable label of one set correspond to the ends having the detectable label in another set. Apart from these two features, the nucleotide sequence of all of the probes amongst the various sets is substantially identical. Within each set of probes the detectable labels are the same and the single end nucleotides are the same. However, amongst the various sets, the single end nucleotide are different and the detectable labels are different, thus providing the differences that distinguish each individual set. Applicant submits respectfully that the language of Claim 20 clearly and unambiguously states this meaning, and Applicant submits respectfully that the language of Claim 20 is clear and definite as filed.".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Although the examiner understands what applicant wants in claim 20 after reviewing applicant's arguments, the limitations recited in the arguments are not recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner suggests applicant to add the limitations recited in his arguments into claim 20 in order to overcome this rejection.

17. Claim 20 is rejected as vague and indefinite since claim 10 and 20 does not correspond each other since the mixture in claim 10 comprises at least one set of free probe (ie., one set of free probe) while the mixture in claim 20 contains at least two set of free probes (ie., two set of probes). Please clarify.

18. Claim 24 is rejected as vague and indefinite since claims 22 and 24 does not correspond each other since claim 22 has at least one sets of free probe while claim 24 has at least two sets of free probes. Please clarify.

19. Claims 25 and 26 are rejected as vague and indefinite because they do not have complete sentences. Please clarify.

20. Claim 28 is rejected as vague and indefinite because it is unclear what it intended because claim 10 and claims 27 and 28 do not correspond each other. According to the definitions of the specification (see pages 9 and 10), "spectrally-addressable" means labeled in a distinguishable manner, "unique" means that the fluorescence emission spectrum of particles in one subset is

distinguishable from the fluorescence emission spectrum of particles of another subset, "spectral address" used in connection with bound particle means the unique fluorescence emission spectrum of the bound particle. These definitions indicate that, (iii) of step (a) of claim 10, the microsphere of one subset distinguishes from that of other subset by their unique spectral address such as their unique fluorescence emission spectrum. Relative amount of a fluorescence dye recited in claim 28 can not be considered as a unique spectral address as recited in claim 10. Please clarify.

Claim Rejections - 35 USC § 102

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

22. Claims 3, 5, 7, 9-13, 15-27, 29, 35, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Chee *et al.,* (US Patent No. 6,355,431, priority date: April 20, 1999).

Claims 3 and 5 are rejected in view of the ambiguity of claims since it is unclear what they intended (see above rejections under 35 USC 112, second paragraph).

Chee *et al.,* teach detection of nucleic acid amplification reaction using bead arrays.

Regarding claim 3, 5, 9-12, 15-21, Figures 7A, 7B, 7C, 7D, 7E and 7F showed a method of OLA/RCA (the oligonucleotide ligation assay/rolling circle amplification). First, a first OLA primer 45 bound to microsphere 10 was hybridized with a target sequence 25 and a second OLA primer 50. Following the addition of ligase, the first and second OLA primers were ligated to form a ligated oligonucleotide 56 (modified primer nucleic acid). Following denaturation to remove the target nucleic acid, the immobilized ligated oligonucleotide was distributed on an array. The immobilized ligated oligonucleotide (modified primer nucleic acid) was detected or was used in RCA wherein an RCA probe 57 and polymerase were added to the array resulting in amplification of the circular RCA probe 58 as recited in claim 9. The modified primer comprised a detectable label, such as a fluorescent label, which was either incorporated by the enzyme or present on the original primer (see columns 3-7, 11, and 44 and claims 1-13 in columns 59-61). Note that the first OLA primer 45 is considered as a spectrally-addressable bound probe while the second OLA primer 50 is considered as a free probe. Chee *et al.*, also taught to the method comprised hybridizing at least a first primer nucleic acid to a first target sequence to form a first hybridization complex, and hybridizing at least a second primer nucleic acid to a second target sequence that was substantially complementary to the first target sequence to form a second hybridization complex (see column 4). Since the second target sequence is substantially complementary to the first target sequence, the sequence of the first primer nucleic acid must be different from that of the second primer nucleic acid. Since these first and second primers can attach to microspheres (see Figures 7A, 7B, 7C, 7D, 7E and 7F), they are considered as two subsets of bound probes that are distinguishable from each other as recited in claim 3. According

to the definition in the specification (see page 9), "substantially identical" means that, when used in connection with the phrase nucleotide sequence, "one or more nucleotides at one or more positions of probes in a subset may differ due to one or more substitutions, insertions, deletions, or combinations thereof but can still be distinguished from probes belonging to another subset and can substantially hybridize to the correct position on the target molecule,". Since these first and second primers have differences in one or more positions and they also consider to be substantially identical as recited in claim 5. Chee *et al.,* also taught the third primer hybridized to a second adjacent domain of the first target nucleic acid while the fourth primer hybridized to a second adjacent domain of the second target nucleic acid (see column 60). Since the second target sequence is substantially complementary to the first target sequence, the sequence of the third primer nucleic acid must be different from that of the fourth primer nucleic acid. Since the third and fourth primer nucleic acids are considered as free probes here, one subset of free probe (the third primer nucleic acid) is distinguishable from other subsets of free probe (the fourth primer nucleic acid). Since these third and four primers have differences in one or more positions and they also consider to be substantially identical as recited in claim 3 according to the definition of "substantially identical". Although claim 3 appears to require two subsets of bound probes and one subset of free probe and claim 5 appears to require two subsets of free probes and one subset of bound probe, since Chee *et al.,* teach two subsets of free probes and two subset of bound probes (see above) and claims 3 does not limit the claim to only two subsets of bound probes and only one subset of free probe while claim 5 does not limit the claim to only two subsets of free probes and only one subset of bound probe, two subsets of free probes and two subset of bound

probes taught by Chee *et al.,* meet the scope of two subsets of bound probes and one subset of free probe as recited in claim 3 or one subsets of bound probe and two subsets of free probes as recited in claim 5. Since the second and fourth primers are considered as free probes with fluorescent labels, Chee *et al.,* teach that the free probes comprising a detectable label at one of their ends as recited in claim 10. Since the first and third primers are bound to microspheres, they are considered as bound probes. Since these microspheres contain optical signature or tag such as fluorophore (decoder beads) so that a bead with an unique signature can distinguished from beads with different optical signatures (see column 45), Chee *et al.,* teach that the microsphere of bound probes of a given subset having a unique spectral address as recited in claim 10. Since the free probes and bound probes bind to different region of the target nucleic acids, Chee *et al.,* teach claims 11 and 12. Since two subsets of free probes have different sequences while two subsets of bound probes with microspheres have different sequences, according to the definition of "substantially identical" , Chee *et al.,* teach claims 15-21.

Regarding claim 7, the ligase used in OLA is considered as a thermostable ligase since the ligation reaction is performed in a certain temperature in order to maximize the activity of the ligase.

Regarding claims 35 and 36, since the microsphere includes amino groups including aliphatic and aromatic amines (see lines 65-67 in column 43 and lines 1-3 in column 44), Chee *et al.,* teach the bound probe comprising a microsphere with a modified moiety wherein the modified moiety comprises an primary amino group as recited in claims 35 and 36.

Regarding claims 13 and 22-24, as shown in Figures 7A, 7B, 7C, and 7D, since the second OLA primer 50 (free probe) is 3' of the first OLA primer 45 and 3' -OH of the first OLA primer 45 ligates with phosphate group of the second OLA primer 50 in the presence of a DNA ligase (see attachment) to form a 3', 5' phosphodiester bond, Chee *et al.,* teach the free probe comprises a phosphate at the other of its end (5' end of the second OLA primer 50). Since 5' end the second OLA primer 50 (free probe) is used for the ligation reaction and its fluorescence label must be in its 3' end and the first OLA primer 45 with modified moiety comprising an primary amino group, Chee *et al.,* teach claim 22 because the phrase " which couples the 5' end of the oligonucleotide of the bound probe to a carboxylic acid group on the microsphere" is only considered as an ability of the modified moiety. Since two subsets of free probes have different sequences while two subsets of bound probes with microspheres have different sequences, according to the definition of "substantially identical" , Chee *et al.,* teach claims 23 and 24.

Regarding claims 25, 26, and 29, since Chee *et al.,* showed that, after the ligation, the immobilized ligated oligonucleotide was denatured to remove the target nucleic acid and then distributed on an array. Finally the immobilized ligated oligonucleotide (modified primer nucleic acid) was detected (see lines 33-47 in column 3). Since above ligation and detection are carried out in a separate reaction vessel, Chee *et al.*, teach claim 26. Alternatively, since Chee *et al.,* showed that, after the ligation, the mixtures was added a second enzyme, a polymerase such that the circular probe was amplified in a rolling circle amplification (RCA) assay (see lines 58-65 in column 3). Since, in the alternative assay, ligation and detection are carried out in a single reaction vessel, Chee *et al.*, teach claims 25 and 29.

Regarding claim 27, since a microspheres with an unique signature such as fluorophore can distinguished from beads with different optical signatures and fluorophores have different signal intensity (ie., emission intensity) based on an excitatory stimulus, Chee *et al.,* teach claim 27.

Therefore, Chee *et al.,* teach all limitations recited in claims 3, 5, 7, 9-13, 15-27, 29, 35, and 36.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. No claim is allowed.

25. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
August 22, 2003

ETHAN WHISENANT
PRIMARY EXAMINER